

Pending Claims After Entry of Amendment

1. (Amended) A composition consisting essentially of a *Helicobacter pylori* membrane fraction protein in a pharmaceutically acceptable form, wherein said protein has a molecular weight that appears to be of the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.

3. (Amended) The composition of claim 1, wherein the apparent molecular weight of the protein is of the order of 50 kDa and the protein is obtainable by a process in which:

- (i) *H. pylori* bacteria are extracted with 1% n-octyl β -D glucopyranoside, followed by centrifugation;
- (ii) a bacterial pellet is recovered and it is treated with lysozyme and subjected to sonication, followed by centrifugation;
- (iii) a centrifugation pellet is recovered and it is subjected to washing with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation;
- (iv) the membrane fraction consisting of the centrifugation pellet is recovered and it is resuspended in aqueous medium;
- (v) the membrane fraction is subjected to an anion-exchange chromatography on a Q-Sepharose column in a 0-0.5 M NaCl gradient, followed by washing in 1 M NaCl;
- (vi) the fraction eluted at the start of washing in 1 M NaCl is recovered and it is subjected to an anion-exchange chromatography on a DEAE-Sepharose column, in a 0-0.5 M NaCl gradient; and
- (vii) the fraction eluted in 0.3-0.4 M NaCl is recovered.

4. (Amended) The composition of claim 3, wherein the protein has as N-terminal sequence the amino acid sequence as shown in SEQ ID NO:1.

5. (Amended) The composition of claim 1, wherein the apparent molecular weight of the protein is of the order of 30 kDa and the protein is obtainable by a process in which:

- (i) *H. pylori* bacteria are extracted with 1% n-octyl β -D glucopyranoside, followed by centrifugation;
- (ii) a bacterial pellet is recovered and it is treated with lysozyme and subjected to sonication, followed by centrifugation;
- (iii) a centrifugation pellet is recovered and it is subjected to washing with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation;
- (iv) the membrane fraction consisting of the centrifugation pellet is recovered and it is resuspended in aqueous medium;
- (v) the membrane fraction is subjected to an anion-exchange chromatography on a Q-Sepharose column in a 0-0.5 M NaCl gradient;
- vi) the fraction eluted in 0.28-0.35 M NaCl is recovered and it is subjected to an anion-exchange chromatography on a DEAE-Sepharose column, in a 0-0.5 M NaCl gradient; and
- (vii) the fraction corresponding to the direct eluate is recovered (absence of NaCl).

6. (Amended) The composition of claim 1, wherein the apparent molecular weight of the protein is of the order of 32-35 kDa and the protein is obtainable by a process in which:

- (i) *H. pylori* bacteria are extracted with 1% n-octyl β -D glucopyranoside, followed by centrifugation;
- (ii) a bacterial pellet is recovered and it is treated with lysozyme and subjected to sonication, followed by centrifugation;
- (iii) a centrifugation pellet is recovered and it is subjected to washing with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation;
- (iv) the membrane fraction consisting of the centrifugation pellet is recovered and it is resuspended in aqueous medium, advantageously in carbonate buffer pH 9.5;
- (v) the suspension obtained in (iv) is centrifuged at about 200,000 x g and the supernatant is recovered;
- (vi) the pH of the supernatant obtained in (v) is reduced to about pH 7, advantageously by dialysing against phosphate buffer pH 7;
- (vii) the preparation obtained in (vi) is subjected to a cation-exchange chromatography on an SP-Sepharose column in a 0 - 0.5 M NaCl gradient, advantageously in a phosphate buffer pH 7; and
- (vii) the fraction eluted in 0.26 - 0.31 M NaCl is recovered.

7. (Amended) A *Helicobacter* protein, or a polypeptide that is derived from the protein by fragmentation, in a substantially purified form, which is recognized by an antiserum raised against the protein of the composition of claim 1.

10. (Amended) A composition consisting essentially of a monospecific antibody that recognizes the protein of the composition of claim 1.

11. (Amended) A composition consisting essentially of a monospecific antibody that recognizes the protein or polypeptide of claim 7.

14. (Amended) A diagnostic method for detecting the presence of *Helicobacter* in a biological sample, according to which the biological sample is brought into contact with the antibody of claim 10 so that an immune complex forms, the unbound material is removed, and the immune complex formed between the sample and the antibody is detected.

15. (Amended) A diagnostic method for detecting the presence of antibodies to *Helicobacter* in a biological sample, according to which the biological sample is brought into contact with the protein or polypeptide of claim 1 or claim 7 so that an immune complex forms, the unbound material is removed, and the immune complex formed between the sample and the protein or polypeptide is detected.

16. (Amended) A process for the purification of the protein of the composition of claim 1 from a biological sample, according to which the biological sample is subjected to affinity chromatography using a monospecific antibody that recognizes said protein or polypeptide.

17. (New) An immunogenic polypeptide fragment of the protein of the composition of claim 1.

18. (New) The composition of claim 1, further consisting essentially of an adjuvant.

19. (New) The composition of claim 1, further consisting essentially of an additional *Helicobacter* antigen.

20. (New) The composition of claim 19, wherein the additional *Helicobacter* antigen comprises a *Helicobacter* urease, or an immunogenic subunit or fragment thereof.

21. (New) The composition of claim 1, further consisting essentially of a *Helicobacter* urease, VacA, CagA/TagA, HspA, HspB, catalase, Hpa, Hpn, HopA, HopB, HopC, HopD, or an immunogenic subunit, fragment, or combination of any of these antigens.

22. (New) The composition of claim 1, wherein said *Helicobacter* membrane fraction protein has a molecular weight that appears on the order of 50 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.

23. (New) The composition of claim 1, wherein said *Helicobacter* membrane fraction protein has a molecular weight that appears on the order of 32-35 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.

24. (New) The composition of claim 1, wherein said *Helicobacter* membrane fraction protein has a molecular weight that appears on the order of 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.

25. (New) A method of preparing a pharmaceutical composition, said method comprising combining the composition of claim 1 with an additional *Helicobacter* antigen.

26. (New) A method of preparing a pharmaceutical composition, said method comprising combining the composition of claim 1 with an adjuvant.

27. (New) A method of preparing a pharmaceutical composition, said method comprising combining the composition of claim 1 with pharmaceutically acceptable carrier or diluent.

28. (New) A composition consisting essentially of a *Helicobacter pylori* protein in a pharmaceutically acceptable form, wherein said protein has a molecular weight that appears to be of the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.

29. (New) A composition consisting essentially of a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS and an additional *Helicobacter* antigen.

30. (New) A composition consisting essentially of a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS and an adjuvant.

31. (New) A method of preparing a pharmaceutical composition, said method comprising combining a composition consisting essentially of a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS with an additional *Helicobacter* antigen.

32. (New) A method of preparing a pharmaceutical composition, said method comprising combining a composition consisting essentially of a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS with an adjuvant.